Inventor: PICKFORD ET AL Serial No.: 10/501,538 Filing Date: 7/16/2004 Examiner: Thomas C. Barrett Group Art Unit: 3733

## **REMARKS**

This is a response to the Office action of November 16, 2005.

Proper titles of been inserted into the specification.

The Examiner has indicated that claims 1-18 (sic) are rejected under 35 U.S.C. 102(b) as being anticipated by Ogle (6,113,636A) as cited in Applicants' IDS. It is to be noted that claims 9-12 were cancelled in the Preliminary Amendment filed on July 16, 2004. Thus, the rejection applies to claims 1-8 and 13-18.

Although the Examiner has correctly observed that the cited prior art has some features in common with the present invention, the crux of the present invention is the recognition that the surface layer must be produced in such a way as to be integral with the metal substrate. The present invention must be clearly distinguished from merely electroplating metallic silver onto an implant: as is clear from page 1 lines 16-23 this simple electroplating approach is recognized as being part of the prior art; and the present invention specifies that, if electroplating is to be used, it should be "followed by diffusion bonding so that the layer becomes integral with the metal of the implant" (page 2 lines 1-3). In contrast, electroplating produces a surface layer which is clearly distinct from the underlying substrate, although attached to it; it is not "integral" with the substrate as required and specified by the present invention.

Turning now to the citation US 6 113 636 (Ogle), this suggests depositing silver onto a medical article, this being

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deposited for example into tissue which forms a part of the medical article; or on and within a biocompatible material such as fabric or tissue (see column 2 lines 46-52 and column 3 lines 18-33). One method of deposition is electroplating, and the deposition of silver being described at column 8 lines 57-67. But no processes are described that produce an implant comprising a metal substrate having a surface layer that is integral with the metal substrate, and the surface layer incorporates a biocidal metal deposited from a solution, as defined in parent claim 1.

The examiner has emphasized that in defining a product, the method steps are to be "given limited weight" because they do not affect the final structure. That is clearly a reasonable approach in some situations — for example layers deposited by electroplating from different salt solutions may be indistinguishable. But as regards the structure obtained as specified in claims 2 and 3, in which a layer is grown out from the metal substrate by an anodizing process, the resulting structure is completely different from anything suggested by the citation. And similarly as regards the structure obtained as specified in claim 7, the resulting structure is distinguishable (e.g. under the microscope) from a simple electroplated implant, because the diffusion bonding step leads to interdiffusion of metal between the substrate and the electroplated layer.

It will also be appreciated that the requirement that the surface layer be "integral" with the metal substrate (as defined in parent claim 1) overcomes a significant problem in the prior art: if you deposit a surface layer on to a metal substrate which is subsequently implanted into the human body, there is a significant risk that the surface layer may become detached from the

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substrate after being implanted (either as a result of corrosion or of wear). This risk is very significantly reduced by ensuring that the deposited surface layer is "integral" with the metal substrate in accordance with the present invention.

In view of the foregoing explanations, reconsideration of the application is requested and allowance of parent claim 1, and the claims depending therefrom, is courteously solicited.

Respectfully submitted,

February 16, 2006

Date

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I hereby certify that this correspondence is being transmitted by facsimile this day to Examiner Thomas Barrett at the United States Petent and Trademark Office, Art Unit 3738, to fax No. 571-273-8300.

Date

Signature